DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR SINGLE HEAD SEMI AUTOMATIC TUBE FILLING, CRIMPING AND SEALING MACHINE	PROTOCOL No.:

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1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of Semi Automatic Tube Filling, Crimping and Sealing Machine (Make: Propack Technology Pvt. Ltd.).
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity.
Production	• Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution.
Engineering	• Review of the Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • To co-ordinate and support the Activity. • To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e. ➢ GA Drawing. ➢ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures. ➢ Details of utilities. ➢ Identification of components for calibration. ➢ Material of construction of all components. ➢ Brief Process Description. ➢ Safety Features and Alarms. • Review of Qualification Protocol after Execution.

5.0 BRIEF EQUIPMENT DESCRIPTION:

The Automatic linear plastic tube filling machine is designed with high speed for filling the plastic tubes and Lami Tubes.

The operator has to feed the product inside the jacketed hopper. The tube insert manually passes to each and every station for performing the filling operation of filling is described thoroughly.

All the safety features are provided in the machine, which are as per the GMP standard and is in compliance with set industrial standards.

STRUCTURAL OVERVIEW:

- **Driving clutch system:** motor, speed reducer, chain, gear wheel.
- **Filling system:** Filling cam, filling travel adjusting device, filling shaft, main valve, nozzle, blowing device etc.
- **Cream Transferring system:** Cam, Transfer travel adjusting device, shaft, pump, hopper etc.
- **Heating system:** Heating cam, shaft, heating drum, heater air fan, temperature control system and cooling system.
- **Cutting system:** Cutting manipulator, cooler etc.
- **Trimming system:** Trimming manipulator
- **Tube output system:** Cam shaft pushing rod etc.
- **Electrical system;** Controlling transformer, frequency inverter PLC set.
- **Optional equipments:** 2P chiller, 0.7 Mpa air compressors.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical variables	Acceptance criteria	Reference
Application: Single head Semi automatic filling, Crimping and sealing machine are designed to fill ointment different weights in different sizes of tubes.	Should be able to filled weight accurately with minimal spillage.	Process Requirement
Working: The machine works on vacuum filling principle.	Filling of material should be highly accurate.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS/LOCATION SUITABILITY:

Critical variables	Acceptance criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	Voltage : 230 VAC Phase : 3 Phase Frequency : 50 HZ & 1.5 Amps.	GMP Requirement
Room Condition	Temperature NMT 25 ºC RH : NMT 55 %	Process Requirement
Compressed Air supply	5-6 bar	Process Requirement

7.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	Critical Variables	Acceptance Criteria
01	**Commercial Data**	
➢	Model	cGMP Model
➢	Manufacturer	Propack Technologies Pvt. Ltd.
➢	Machine name	Automatic filling , Crimping and sealing machine
02	**Mechanical Data**	
➢	**Dimensions**	2220 X 1000 X 1520
➢	**Weight**	0.60 tons approx.
03	**Electrical Data**	
➢	**Machine Voltage**	230 Voltage AC, 3 phase, 50 Hz
➢	**Power Supply**	230 Voltage AC, 3 phase, 50 Hz
04	**Main motor details**	
➢	**Type**	RV7515 Y1.1
➢	**Power supply**	230 V, 50 Hz; 4.8 A
➢	**Qty**	1 Nos.
06	**Buttons**	
➢	**Make**	Schneider
➢	**Model**	XB2-BD21C
➢	**voltage**	230 V
➢	**Qty**	Red-01 Nos., Green-01 Nos.
07	**Contactor**	
➢	Make	Schneider
➢	Model	LC1-D1810
➢	Qty	01 No.
08	**Stepper Motor**	
➢	Make	Mige
➢	Model	FHB31913-H
➢	Qty	01 No.
08	**Coder**	
➢	Make	Omron

S.No.	Critical Variables	Acceptance Criteria
➢	Model	E6B2-CWZ6C
➢	Qty.	01 No.
09	**General Specification**	
➢	Heat sealing Power	3KW
➢	Tube material	lami tube
➢	Tube diameter	12-50
➢	Filling accuracy	≤± 1 %
➢	Filling volume	3-250 ml , adjustable
➢	Product capacity	1800-4200 adjustable
➢	Water Circulation	5 LPM

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material of construction
1.	Hopper	SS 316 L
2.	Filling valve	SS 316 L
3.	Filling nozzle	SS 316 L
4.	Filling pump	SS 316 L
5.	Bearings	SS 304
6.	Sealer	MS
7.	Cutter	HCS
8.	Station cup	Polymerized Plastic
9.	Heater	SS 304
10.	Lifting shaft	2CL13
11.	Tube chamber	Plexiglas plate
12.	Piston	Teflon

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Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

7.5 SAFETY:

Critical Variables	Specified Function	Reference
Safety door switch	Operator Safety.	Safety Requirement
Torque limiter	For Operator Safety.	Safety Requirement
Emergency stop button	For Motor, equipment protection & Operator Safety	Safety Requirement
MCB inside the control panel to cut off the power supply if any short circuit occurs.	For Operator Safety	Safety Requirement
Safety labels on the machine to avoid the hazards.	For Motor, equipment protection & Operator Safety	Safety Requirement

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Sign/Date: ……

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the Automatic Tube Filling, Crimping And Sealing Machine.	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical know how, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) Specifications and Requirements as specified in P.O. and URS.

(2) Operating and service manual for Double head fully automatic filling, closing and sealing machine.

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Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

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Reviewed By
Manager QA
Sign/Date: ……

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents.

9.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
VFD	:	Variable frequency Drive
SS	:	Stainless Steel
MOC	:	Material of Construction
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
P.O	:	Purchase order
LPM	:	Liter per minute
db	:	Decibel
PLC	:	Programmable logical controller
HMI	:	Human Machine Interface
RH	:	Relative Humidity
SS	:	Stainless Steel

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			